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Regulation of Hazardous Substances in Electrical and Electronic Equipment in Europe

Manufacturer's perspective

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<p>Electrical and electronic equipment (EEE) constitutes a major waste source in Europe, with projected volumes as high as 12 million tons in 2020. Historically, it has incorporated a variety of chemical substances, now identified as hazardous to both the human health and the environment, such as heavy metals and various organic compounds. In order to limit the incorporation of such substances into electronics, a number of harmonised European legal acts were introduced since the beginning of 2000s as a part of a trend to create a single European market for goods and services. The hazardous substance legislation, being ranked among the most burdensome by the manufacturers, places a variety of requirements on legal manufacturers of electrical and electronic equipment, depending on the nature of the product, volumes placed on the European market, and a number of other factors.</p> <p>The purpose of this thesis was to research the requirements such legislation places on EEE manufacturers, compliance approaches available to them and the impact of the legislation on the manufacturer's operations and the environment. The study was based on the analysis of European legal acts and both official and unofficial guidance documents, publications from market surveillance authorities as well as topic-related research literature.</p> <p>The state of compliance has not yet been analysed systematically, but a number of small-scale studies, though purely informative, suggest a compliance state can be described as compromised. Recent non-compliance rates range between 19.7% and 40%. Manufacturers struggle to comply with the requirements due to both a lack of expertise and the economic costs of compliance, along with their position in the supply chain; however, the reduction in hazardous chemicals, in particular heavy metals, in electronic waste specifically linked with the new harmonised legislation has already been established.</p>	
Keywords	hazardous substances, compliance, electrical and electronic equipment, EEE, RoHS, REACH

List of Abbreviations

SME	Small and medium-sized enterprise
RoHS	Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
EEE	electrical and electronic equipment
EEA	European Economic Area
ECHA	European Chemicals Agency
CE	Conformité Européenne, conformity marking of specific product categories placed on the market in EEA
NLF	New Legislative Framework
SVHC	substances of very high concern
WEEE	waste electrical and electronic equipment
EHSR	essential health and safety requirements
SDS	safety data sheet

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1 Introduction

With the ever increasing number and complexity of electrical and electronic equipment (EEE) placed on the European market, the potential for exposure of human beings and environment to dangerous constituents of such equipment during normal use or at the stage of waste is not to be taken lightly.

According to the European commission, e-waste, or waste from electrical and electronic equipment (WEEE) is a major stream of waste with a strong growth potential – from 9 million tons reported in 2005 to 12 million tons expected to be produced in 2020 (European Commission, 2016b). While it is important to manage e-waste as the equipment reaches the end of its life, which is achieved through compliance with the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE Directive), a piece of European legislation first enforced in 2003 and recast in 2012, it is also crucial to prevent the introduction of potentially hazardous contents prior to placing such equipment on the European market, which happens significantly earlier than a stage at which the WEEE Directives comes into consideration.

Electronics are historically known to incorporate heavy metals such as lead in solder or mercury in batteries and a multitude of organic compounds often as fire retardants (Ewasteguide.info, 2009), which might be damaging to both human health and the environment. The problem is well recognised by EU legislators; and for decades a number of different level legal acts and agreements both on national and international level has existed, often overlapping and contradicting. The current trend to harmonise the European legislation to create a single market for goods and services resulted in arguably the world's best regulatory regime for chemicals in consumer products, which is proven by efforts to emulate it at least in part in China and the US (Biedenkopf, K. 2012); however, it is still far too complicated for the understanding of small or medium-sized EEE manufacturers in the EU.

The multitude of regulatory requirements a company manufacturing electrical and electronic equipment faces may be related to product safety, electromagnetic compatibility, energy efficiency, customs export and import rules, packaging, labeling, etc. But arguably the most overlooked are regulations related to hazardous substances contained in the item. Outside of the chemicals industry, the level of awareness and understanding of

the said regulations is worryingly low. In the EEE industry, they are often misinterpreted, misunderstood and considered lastly if, unfortunately, at all.

While an electric shock and electromagnetic interference are apparent risks that can be easily tested, chemicals hidden within the components of appliances often evade the attention of both manufacturers and market surveillance authorities. Substances do not create an immediate and obvious risk to the user, are not visible to the naked eye and moreover, might pose a risk only at the stage of waste.

The availability of various guidelines documents issued both by the regulating authorities and independent researchers improves the compliance status significantly. However, problems might be caused not so much by the limited information, but rather by an overabundance of it, which may be overwhelming for a small staff of companies not having designated compliance departments to analyze and consolidate the data on requirements.

The purpose of this thesis is to summarize the European regulatory requirements of chemicals which govern electrical appliances being placed on the European market, identify the specific obligations of a manufacturer of such appliances and highlight the overall compliance situation and trends, as well as approaches to achieve and maintain the compliance status, available to companies placing EEE on the European market.

The research is based on empirical information obtained during normal daily work in the area of compliance and approvals, an analysis of publicly available company documents of selected companies referred in the text, analysis of legal acts and both official and unofficial guidance documents, publications from market surveillance authorities as well as topic-related research papers.

2 Theoretical background

This chapter covers the basic legal and economic concepts, relevant to the understanding of the regulatory situation of hazardous substances in EEE and to determining the scope of such regulations' applicability.

2.1 European single market

At the present stage of the development of the European Union, which is a result of more than 40 years of integration, a single market for goods is an economic reality. It contributes to the eliminating of barriers for the free movement of goods, creates unified rules which economic operators must comply with while ensuring equal level of protection of consumers and the environment throughout the territory of the EU. According to the European commission website on Single market (European Commission, 2016a), industry sectors in EU can be classified into harmonised and non-harmonised. For harmonised sectors, legal frameworks exist at the European level. Non-harmonised sectors still exist as well; here the national legislation governs the legal regimes.

For the majority of sectors, including electronics industry, such harmonisation happens at the level of essential health, safety and environmental protection requirements. Technical details are contained in the industry-developed technical specifications and harmonised standards, mandated by the European commission, but created by independent 3rd parties – industry associations. They are voluntary by nature and a manufacturer has a right to decide whether to use the harmonised standards, national standards, other technical specifications or to apply the legal requirements directly. Harmonised legal acts are usually issued in the form of Directives, which require implementation by national legislation on the territories of member states.

For some sectors, however, including the chemicals sector, detailed technical requirements are part of the European legislation. They are often issued in the form of Regulations – legal acts that are directly applied in the territory of the member states. Hazardous chemicals in electronics are, therefore, subject to both of these harmonised legislation approaches.

The Union harmonisation legislation often operates the following terms: placing on the market, making available, actors in supply chain or economic operators (such as manufacturer), all of which have a specific meaning in its context and are crucial for the determination of applicable requirements.

According to the European Commission Guidance on the implementation of product rules, more commonly referred to as the “Blue guide” (2015), the following definitions are commonly used in legislation:

A manufacturer is “any natural or legal person who manufactures a product or has a product designed or manufactured, and places it on the market under his own name or trademark”. This definition often causes confusion as it goes against the common sense in cases where the supply chain actor’s involvement with the product is limited to attaching a label with own brand name, yet for all intents and purposes of Union legislation such entity would be considered a legal manufacturer.

Making available is “supplying for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge”, as stated in Article 2 of Regulation (EC) No 765/2008 and Article R1 of Annex I of Decision No 768/2008/EC. The Blue guide further specifies, that the concept “refers to each individual product” (European Commission, 2015).

Placing on the market is “making the product available for the first time on the Union market”. This is a very important point in a product’s life cycle, since this is where commonly Union legislation requires the product to demonstrate compliance.

2.2 European approach to regulating chemicals

At the highest level, all chemical substances which are manufactured, imported, used or placed on the market in the EEA are governed by the Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals known as REACH, which entered into force in 2007. The Regulation applies to chemicals on their own, in mixtures and in articles (products), which in practice means that it applies to the entire range of industrial sectors where chemicals are dealt with directly or indirectly, though primarily affecting chemical industries, and covers essentially every object created or brought into the EEA on a professional basis.

This legal act incorporates technical requirements and is subject to direct application in the member states. The European Chemicals Agency (ECHA) is responsible for maintaining REACH. The approach to regulating chemicals is to document all chemicals, used in the EEA in a database based on submissions of the manufacturers and importers of such chemicals. Such submissions or registrations include the known uses and risk assessments and management of the chemicals in question. Safety risks are identified and the chemicals are classified accordingly. Safety instructions should be created in order to mitigate the identified risks. According to the Summary of the Regulation (EC) No 1907/2006 (European Chemicals Agency, 2015), the aim is to also promote scientific

research to find safer alternatives for the identified hazardous chemicals. All registered chemicals should be used according to their identified and assessed uses.

Such approach places a relatively high burden primarily on the chemicals industry (by removing it from the member state or European authorities); however, this is the industry most equipped to carry out such a task.

Based on the risk assessment and available safer replacements, the identified chemicals are either restricted for certain uses (where such alternatives are available); identified as a substance of very high concern (SVHC) and either made subject to the authorisation from ECHA for a certain use, where no economically viable alternatives are present, and the risks are sufficiently high but adequately controlled or placed into a Candidate list for the inclusion into the authorisation list; or no controls are applied. The classifications are fluid and subject to change, since they are based on the current state of the scientific development, known risks and the presence of safer alternatives. The term “adequately controlled” here means that the exposure threshold level determined for the substance is never reached in the course of the authorised use, whether through intended or unintended releases. Methodologies exist for determining such thresholds for different classes of dangerous substances.

The objectives of different control measures vary, thus determining how the risk of the substance will be assessed for the purpose of applying a control measure. REACH defines “chemicals”, “mixtures” and “articles” as well as actors of a supply chain. The combination of terms would determine the applicable requirements.

Every consumer product industry is covered by REACH, however, there is also sectoral legislation, which may regulate the use of certain chemicals in the industrial sector in question. Such legislation may contain different procedural requirements (usually more precise than REACH) and with respect to chemicals it regulates and may contain different maximum permitted concentration limits. Such sectoral legislation is considered to provide an adequate level of protection with respect to chemicals it covers, and the rest are governed by REACH.

For the electrical and electronic industry, a number of such sectoral legislative acts exist. The first and foremost is Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) – a CE marking

Directive, part of New Legislative Framework (NLF) package, which will be discussed in detail further. It gives a definition of electrical and electronic equipment, for which the restrictions for substances apply. At the moment, the list of restricted substances contains 10 items, out of which only 6 are active restrictions. In addition, a number of exemptions can be used for a specific product or application. Unlike the normal case with the sectoral legislation, it is applied without prejudice to REACH, which means in case of contradiction REACH should prevail. As of now, just one such overlap has been identified in a European Commission study of REACH (2013a): RoHS and REACH both restrict cadmium and both provide exemption for it, REACH permits it in “electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed”, while RoHS permits it in electrical contacts without further conditions of application.

Another one is Directive 2006/66/EC of the European Parliament and of the Council on batteries and accumulators and waste batteries and accumulators (Battery Directive). It applies to all batteries and accumulators, placed on the EEA market, including the ones which are parts of EEE. Batteries are exempt from RoHS according to recital 14 of RoHS preamble, but not from REACH requirements. Even though the Battery Directive is more known to manufacturers for its labelling, collection targets and producer registration requirements, hazardous substances restrictions are essential part of it as well. Mercury and cadmium are the substances regulated by the Battery Directive.

This may lead to a rather complicated process to identify the applicable hazardous substances related requirements for an individual appliance. If we take a radio containing a battery as an example, it will be subject to: Battery Directive – which will restrict hazardous content in battery only; RoHS, which will apply to the entire unit except the battery; and REACH – for the substances, not covered by Battery and RoHS Directives, controlled for the uses in electronics, and it will apply to the entire unit.

To add another layer of complexity, different applicable legal acts may have a different scope with respect to a product life cycle. REACH restrictions apply also to the use of chemicals, whereas RoHS limits the chemical content only in the finished product at the moment of placing it on the market, and excludes catalysts and other similar chemicals, which would not be present in the end product (they would be regulated by REACH rules for the use of chemicals).

REACH and sectoral directives are complementary pieces of legislation, yet they followed a different route into existence and have different objectives. Thus the methodology for inclusion of substances in controlled lists differs as well. It pays off to be aware which substances currently under review are likely to be controlled in the near future.

The special objective of RoHS Directive 2011/65/EU is “environmentally sound recovery and disposal of waste” in addition to protection of human health and the environment, as stated in the Article 1. That means that the substance itself might not pose danger during normal use, but will prevent the equipment from being treated as waste in a sounder way, such as reuse or recycling. However, it does not take into account the risks associated with substance manufacturing, unlike REACH.

2.3 New Legislative Framework and CE marking Directives

New Legislative Framework (NLF) is a package of legal acts, adopted in 2008, aimed at unifying conformity assessment and market surveillance procedures for a set of sectoral directives, all of which share a conformity mark – CE mark. All of the sectoral directives contain essential health and safety requirements (EHSR) and administrative (documentation) requirements and a reference to available conformity assessment modules for this specific directive.

Conformity assessment is a set of measures or processes, aimed at evaluating and confirming that the product indeed complies with the EHSR. Permitted modules are described in Decision No 768/2008/EC. Regulation (EC) No 765/2008 specifies market surveillance procedures. The latter one, being a Regulation, has a direct application in member states; it clarifies the responsibilities of surveillance and assessment national authorities, which have to be appointed by the member state to monitor economic operators' compliance with the essential requirements of the sectoral legislation.

These legal acts are complemented with a list of ever changing harmonized standards – the standards, references to which are published in the Official Journal of the European Union and which are developed on an EU mandate by a number of designated international bodies, to reflect the state of the art in compliance with the essential health and safety requirements of the EU Directives. The following Figure 1 gives a graphical representation of NLF structure.

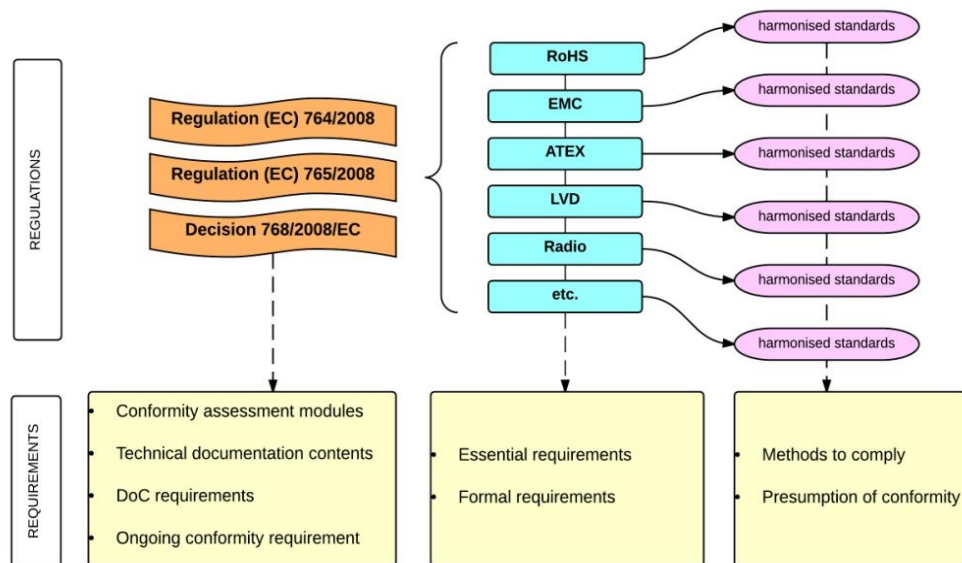


Figure 1. NLF structure

Conformity, which is a state where the product fulfils all the EHSR is a key term of NLF. Harmonised standards, which are voluntary by nature, nonetheless provide presumption of conformity. Being applied, they permit the manufacturer to skip one step in their conformity assessment process – demonstrating how selected technical specification helps to comply with EHSR. This makes them in reality essentially mandatory requirements. The Blue Guide covers a process of conformity assessment and the role of harmonised standards, which is represented in the Figure 2.

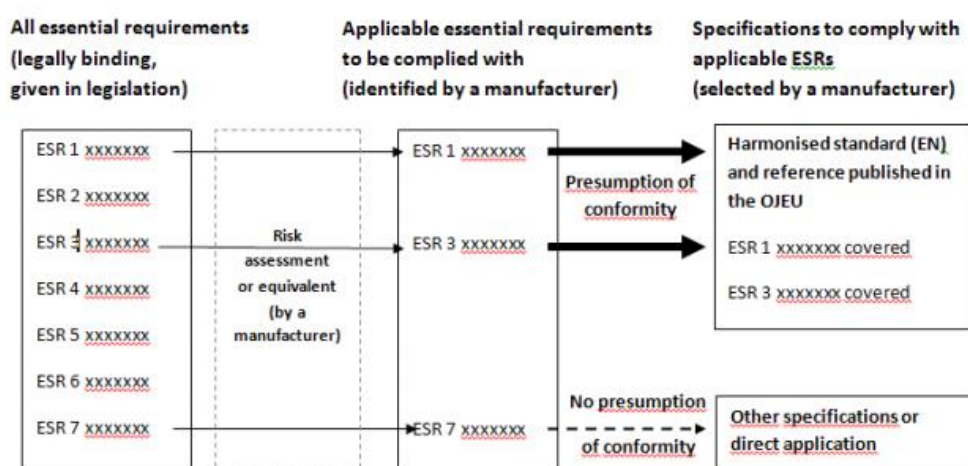


Figure 2. The role of harmonised standards when complying with applicable essential requirements identified by a manufacturer (European Commission, 2015)

As the NLF was developed to eliminate trade barriers in addition to unifying the safety requirements on the European scale, the final responsibility for assessing the conformity of the product is placed exclusively on the manufacturer, involvement of the state authorities and other official organizations is minimized in most cases to the market surveillance and only where the risk of non-compliant product is overwhelmingly high. Some modules of conformity assessment require the use of a Notified Body – a pre-approved 3rd party which evaluates a representative sample of the product and/or quality procedures used by the manufacturer to substantiate the claim that the products comply with the only mandatory kind of requirements of the NLF – essential health and safety requirements of the applicable Directives. For RoHS such option is not required.

RoHS along with a number of other sectoral EU Directives form a set of so called CE-marking Directives, sharing common administrative requirements: establishing an internal production control procedure, generating and maintaining a Technical file as a result of compliance efforts, creating a Declaration of Conformity with prescribed elements and labeling the product with a CE mark as an indication the product is in conformity with all applicable essential health and safety requirements of all applicable CE marking Directives.

The purpose of the NLF is as well to shift the focus of surveillance efforts from pre-approving product prior to placing on the market to ensuring its compliance is maintained throughout its lifecycle, as essential health and safety requirements along with state of the art technical specifications undergo changes.

Therefore, being a part of NLF, RoHS leaves the manufacturer with a limited number of allowed compliance strategies as well as places requirements to generate and maintain prescribed documentation in support of a compliance claim. The manufacturer is equally penalized for defects in compliance procedures, documentation and actual presence of restricted substances.

Since electronic product is usually subject to at least 2 of the CE marking Directives, which have common conformity assessment and production control requirements, it is reasonable to carry them out simultaneously to all applicable directives.

Additionally, international quality standard ISO 9001 is harmonized to the NLF package as a whole. This means implementation of ISO 9001-based quality management system

which contains elements required by NLF would give presumption of conformity with respect to internal production control requirements and, where applicable, quality assurance system requirements.

3 Manufacturer's responsibilities for hazardous substances in EEE

The manufacturer or producer - terms, which are commonly used interchangeably, is solely responsible for compliance with the applicable product requirements. Its obligations per different legal acts may vary depending on the nature of the product, volumes in which it is placed on the market, the date of placing on the market, the substance it may contain and other factors. This is why it is important to review potentially applicable obligations and exemptions independently for each legal act. The process of determining the legal responsibilities or compliance risk assessment should also include reviewing the scopes of the legal acts, both geographical and product, and exempt applications, to determine if the equipment is subject to the legislation at all and which of the specific requirements the manufacturer will have to comply with.

3.1 Responsibilities per REACH Regulation

Requirements for different actors in supply chain of a chemical vary to a great extent. In the chemical industry producers of chemicals and mixtures are subject to a greatest degree of control. The tonnage of regulated chemicals affects the scope of responsibilities as well. Thus the electronics manufacturing industry, with the exception of the largest companies working with massive production volumes, are subject to the least strict requirements per REACH.

It is worth mentioning that the producers of EEE are usually lacking expertise related to the chemicals management. For their convenience, a number of tools exist on ECHA website to help evaluate the scope of applicability of certain requirements. A good way to begin REACH compliance risk assessment is by using an interactive Navigator tool on ECHA website, (ECHA, n.d.). Several guides were issued by ECHA as well to clarify the approach to the identification of requirements of the articles producer. This chapter is mainly based on these documents and tools.

A first step is to determine how the produced equipment will be classified. As a rule of thumb, all EEE belongs to a category "articles". The following definition is given to it in the Regulation(EC) No 1907/2006 in Article 3(3): "an object which during production is

given a special shape, surface or design which determines its function to a greater degree than its chemical composition". Generally, everything which cannot be considered a pure chemical or a mixture is an article.

Articles can be very simple and extremely complex. For the purposes of REACH obligations application, an article was earlier defined as an end-object or a finished equipment. A further clarification was given to a definition by the judgment of the Court of Justice of 10 September 2015 in the case C-106/14 (2015). According to it, an article would be each individual component, i.e. the simplest constituent of a complex product to which the definition of an article can apply. This was earlier a principle applied in the Northern countries – so called *once an article, always an article*. As a consequence, all threshold or cut-off values are calculated at the level of such constituent article. Since there is a multitude of components in electronics, the concentration should be calculated for them individually.

Not all of the electronic components are articles only. A printer cartridge is a good example of an article which is a container for a mixture – a printing ink or a powder. The container will be subject to article obligations as follows. With respect to the mixture the manufacturer will be a mixture downstream user (presuming the mixture is purchased ready-made from an upstream supplier) and a mixture supplier, and might need to consider if the substances in mixture need to be registered, or whether a safety data sheet needs to be included with it. The vast majority of electrical items are, however, just articles.

The obligations of the articles manufacturer under REACH are Registration; Notification; and Communication of information. The European Chemicals Agency (2015) provides a breakdown of obligations of the articles manufacturers in Table 1 below; concentration thresholds are given in percentage of the weight of the substance per weight of the article.

All of the criteria and none of the exemptions should be present for the obligation to apply. The term articles supplier here means any actor of the supply chain, placing the product on the market, including the manufacturer.

Table 1. Main obligations for substances in articles (European Chemicals Agency, 2015)

Obligation:	Registration of substances in articles	Notification of substances in articles	Communication of information on substances in articles
legal basis in REACH Regulation	Article 7(1)	Article 7(2)	Article 33
actors concerned	article producers and article importers	article producers and article importers	article suppliers
substances concerned	substances intended to be released from articles	substances included in Candidate List of Substances of Very High Concern for authorisation	substances included in Candidate List of Substances of Very High Concern for authorisation
tonnage threshold	1 tonne per year	1 tonne per year	-
concentration in article threshold	-	0.1% (w/w)	0.1% (w/w)
exemption from obligation possible on the basis of:			
registered for that use	yes	yes	no
exposure can be excluded	no	yes	no

Though not absolutely impossible, it is highly unlikely that the registration requirement will apply: even if the substance which is intended to be released from an article, is placed on the EEA market above the tonnage threshold, which is calculated as the total weight of the substance in question (both the part that is subject to release and not) in all of the articles from that manufacturer, the likelihood of that substance not being registered a whole decade after REACH has come into effect is negligible.

The second and the third obligations are for the substances in articles, which are included into the Candidate list. The Candidate list, which is not a part of the REACH Regulation itself and can be found on the ECHA website contains the substances that were identified as being hazardous. Such identification is based on substances' internal properties only, the risks of them causing actual damage are not considered at this stage. Guidance for Suppliers of Articles (Belgian Federal Public Service, 2013) summarizes that the classes of the substances which may be included into the Candidate list are the following:

CMR – carcinogenic, mutagenic or toxic for reproduction (only categories 1A and 1B);

PBT – persistent, bioaccumulating and toxic;

vPvB - very persistent and very bioaccumulating;

substances for which there is evidence for equivalent level of concern having probable serious effects to human health, such as endocrine disruptors.

At the time of writing this thesis, the Candidate list included 168 substances. The list is updated twice a year following a formal procedure.

The second obligation is somewhat more likely to concern the manufacturer, since some of the substances included in the Candidate list, for example, fire retardants, can easily be found in constituent articles, such as printed circuit boards in concentrations above the cut-off values, and larger manufacturers are at risk of achieving the tonnage threshold. However, exemptions are almost always will be applicable; the situation where a substance is used in amounts above the tonnage threshold and is not yet registered for such use is extremely unlikely if at all possible.

Thus the only obligation that the manufacturer realistically can and will be subject to is the information communication obligation.

According to Article 33 of the REACH Regulation (EC) No 1907/2006,

1. Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1% weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.
2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1% weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 days of receipt of the request

Part 1 of the Article 33 requires providing information to a recipient – a professional user of the substance or a distributor. Such information must be provided together with the article or later – immediately upon inclusion of the substance into the Candidate list. No prior request is required neither the time is given to fulfill it, as in the case of a customer (an individual end user).

To fulfill this obligation, the manufacturer needs to be fully aware of the substances which are under review for inclusion into the Candidate list before a decision is made in order to evaluate the products, including the ones already on the market, sold earlier or even

not produced anymore. The manufacturer has to preserve the records of the transactions to identify the recipients of the articles and the suppliers of the substance.

As is fully clear at this stage, the manufacturer is highly dependent on proper communication within the supply chain. Testing all the components of all the products, including the ones the production of which has been discontinued, for all the current SVHC and the subsequent additions is economically unfeasible. Moreover, it is not recommended as a preferred method for establishing compliance by the ECHA in Guidance for substances in articles (2015). Instead, it recommends a few other approaches to fulfilling the communication of information obligation: pro-active requests for information with clarification of why it is needed for specific substances which are at risk of being present in the particular article; inclusion of limitations on the use of SVHC in the legal contracts with the suppliers (note, that they have to be either updated twice a year or include a reference or a link to the latest Candidate list edition); enquiries for suppliers' certifications that the SVHC were not used in manufacturing of the supplied components.

In the same document an emphasis is put on the presence of a Quality management system. Normal quality procedures include the supplier and the product evaluation and can seamlessly integrate REACH compliance measures.

Another obligation which is not specific to the article producers is to comply with restrictions under REACH. A restriction means that a substance, listed in Annex VII is subject to a prohibition of use and may be subject to certain conditions. If the prohibition is complete and unconditional, purchasing from EU suppliers should in principle guarantee no such substance is found in their products. When the prohibition is subject to conditions, such conditions must be communicated by suppliers of substance in the form of a safety data sheet (SDS) or another form. The manufacturer of an electronic product might be at the end of a long line of downstream users, and even if such information was provided by a substance or mixture supplier according to Article 32 to the first such downstream user, it might not end up being properly communicated to the last one.

If at some point along this supply chain a product crosses the border, especially if it is already an article, the chances are even higher for the information on a restricted substance and conditions of use to be lost, miscommunicated or not considered at all. Possible applicable restrictions are therefore easy to overlook in electronics manufacturing. The ECHA advises in its Navigator tool to periodically review Annex VII in order to identify

potentially applicable restrictions, but in reality most of the electronics manufacturers do not have any internal knowledge to process such information. It is rather common that the information on restrictions is not flowing through the supply chain at all.

It would be advisable to at least include a clause on REACH restrictions as a contractual obligation for the suppliers. It might result in them providing the information they otherwise would have considered irrelevant due to the lack of expertise.

3.2 Responsibilities per RoHS Directive

As is the case with REACH, RoHS requirements differ for the supply chain actors; however, here the manufacturer of EEE will be subject to the greatest scope of responsibilities.

First of all, the RoHS Directive 2011/65/EU provides a definition of an electrical and electronic equipment in Article 3 (1) and (2):

electrical and electronic equipment' ... means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current;
...'dependent ' means... needing electric currents or electromagnetic fields to fulfil at least one intended function.

Additionally, the Directive categorises equipment in scope; certain categories are not yet covered by its requirements. It includes a number of general permanent exemptions for specific product types and uses, and several exemptions for certain categories and applications which are subject to expiration, which is why it is reasonable to first evaluate the nature of the product since it would mainly determine the scope of manufacturer's obligations.

Directive 2011/65/EU classifies EEE into 11 categories, some of which are not yet in scope of it. According to Annex I, these categories are:

1. Large household appliances.
2. Small household appliances.
3. IT and telecommunications equipment.
4. Consumer equipment.
5. Lighting equipment.
6. Electrical and electronic tools.
7. Toys, leisure and sports equipment.
8. Medical devices.

- 9. Monitoring and control instruments including industrial monitoring and control instruments.
- 10. Automatic dispensers.
- 11. Other EEE not covered by any of the categories above.

Categories 1-7 and 10 were included in the previous edition of the RoHS Directive and therefore were in scope of the new RoHS Directive since its entry into force. Newer categories 8 and 9 will gradually be introduced into the scope by July 2017 and the catch-all category 11 comes into scope in 2019.

Permanently excluded products are listed in Article 2 (4). These are mainly standard exemptions for military, space and research equipment, in addition to almost all kinds of vehicles, implantable medical devices, large scale equipment and, interestingly enough, photovoltaic panels. Additional exemptions are listed in Annex II (apply to all categories for a specified use) and Annex IV (categories 8-9 only) and are subject to expiration. They might or might not be extended after the expiry date for a limited time based on the state of the technical and scientific progress.

The current list of restricted substances including their permitted maximum concentration values is not uniform either. Listed in Annex II, they are:

- Lead (0,1 %)
- Mercury (0,1 %)
- Cadmium (0,01 %)
- Hexavalent chromium (0,1 %)
- Polybrominated biphenyls (PBB) (0,1 %)
- Polybrominated diphenyl ethers (PBDE) (0,1 %)
- Bis(2-ethylhexyl) phthalate (DEHP) (0,1 %)
- Butyl benzyl phthalate (BBP) (0,1 %)
- Dibutyl phthalate (DBP) (0,1 %)
- Diisobutyl phthalate (DIBP) (0,1 %)

The latter 4 substances, which are the latest addition to the list, will not be restricted for categories 1-6 and 10-11 before 2019 and for categories 7-8 – before 2021. Category 7 is not subject to restrictions of DEHP, BBP and DBP, since they are restricted for such uses by REACH, the legal regime of which will prevail for them.

Once it has been established that the product is in scope of the RoHS Directive, the category and applicable exemptions identified, the manufacturer can proceed to identify the obligations. Similar to all CE marking NLF-aligned Directives, these obligations would be comprised of EHSR, procedural and documentation requirements and enumerated in Article 7 of the RoHS Directive.

The essential health and safety requirements are simple and straightforward – set in Article 4, they prohibit placing on the market of the in-scope non-exempt equipment which contains restricted substances above the given concentrations per weight of each homogeneous material. Such material as defined in Article 3 (20) is of uniform composition and cannot be separated into different materials by mechanical actions. Solder, glue, paint layer or plastic cover will be all homogeneous materials.

Procedural or administrative requirements prescribe that the manufacturer establishes internal production control (module A of Decision 768/2008/EC – the self-certification conformity assessment procedure where involvement of 3rd parties is not needed), would have the procedures to maintain ongoing compliance of the series production and to adequately react where non-compliance has become known, including informing the market surveillance authorities.

Documentation requirements are to create a strictly defined “technical documentation”, issue a Declaration of conformity with mandatory elements per Annex VI and have them available for the market surveillance authorities for 10 years after the product has been placed on the market, keep a register of non-conforming products and attach the label the form and contents of which are also strictly regulated.

In practice, the process of creating the technical documentation would be equivalent to carrying out the conformity assessment. The only standard EN 50581:2012 harmonised to the RoHS Directive has been issued by the European Committee for Electrotechnical Standardization (CENELEC, 2012) and covers “Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances”. Figure 3 below describes the process of generation of such documentation and its prescribed contents.

The process is heavily based on a risk assessment. The first step requires assessing the materials for the risk of restricted substances being present above the permitted values. Moreover, the manufacturer may rely on published literature and publications from EEE industry associations or on historical likelihood of finding such substance in a certain component, which all are recorded and documented sources. It is assumed that the results of such assessment need to be documented and substantiated with recommended types of the evidence material.

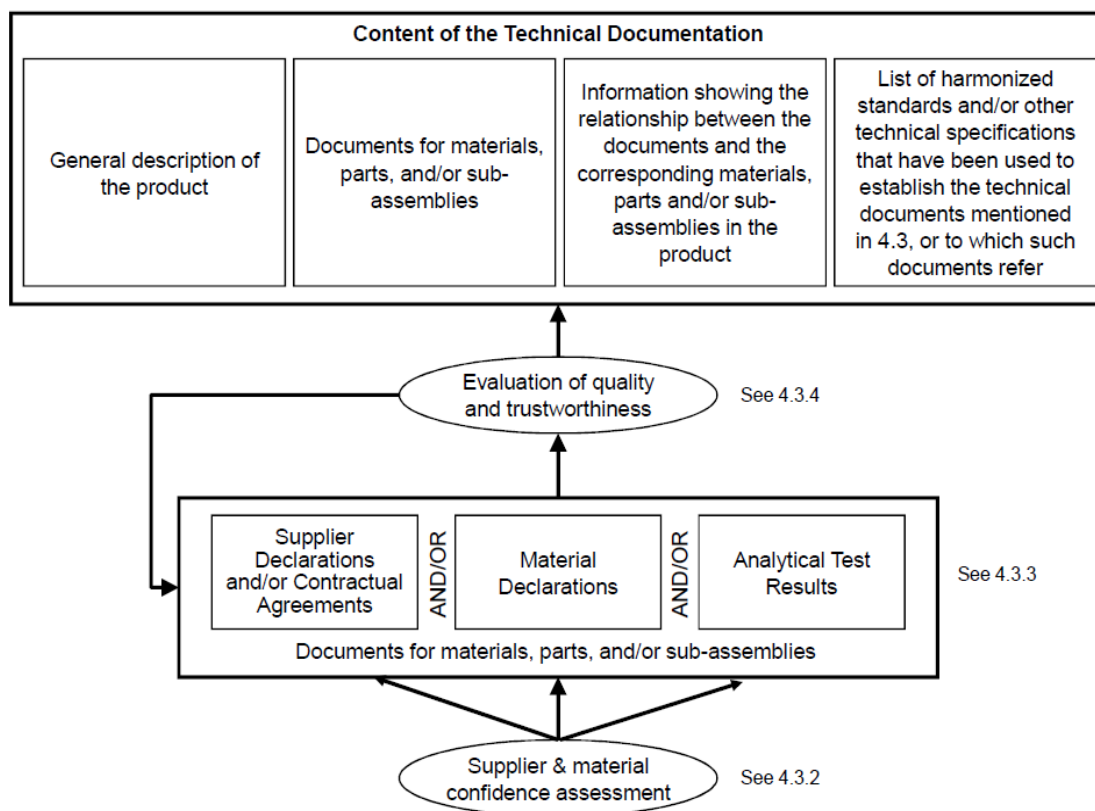


Figure 3. Schematic representation of the process to create technical documentation (CENELEC, 2012)

Next, the trustworthiness of the supplier needs to be evaluated, based on the previous experience of interactions with the supplier organisation, such as audits and inspections. Both assessments are permitted to be carried out within a Quality Management System framework.

As a result of a combined degree of risk of both supplier and nature of the component, a decision on types of permitted supporting documentation or a combination thereof should be made. Only three types are permitted, and their contents are described in the standard. Moreover, they must be evaluated with respect to their source and content in order to establish that they indeed can indicate component's state of compliance.

The supplier declaration contains essentially nothing more but a statement, that the restricted substances are present below the permitted levels. The contract will contain the same information only as a requirement from the manufacturer. Both must be appropriately signed. Before the recast of the RoHS Directive, this type of supporting document was de-facto the only type ever collected or requested. Nowadays it is permitted only if

the combined risk of the manufacturer and supplied parts can be demonstrated to be low.

The material declaration needs to contain the information on the specific substances content in the supplied part. For the purposes of ensuring consistency of information flow throughout the industry, the recommended format is according to the non-harmonised standard EN 62474 “Material Declaration for Products of and for the Electrotechnical Industry” from International Electrotechnical Commission. The standard permits two types of declarations – the so called yes/no type and the full material disclosure type. The first one is an exhaustive list of substances of interest, where a supplier can state whether they are present above the limits or not by ticking either of the yes or no boxes. The latter one is a breakdown of the parts material composition; and further on the chemical composition of each material. Both declarations can be generated based on test results or the information obtained from the supply chain.

The third permitted type of a supporting document is an analytical test result. Such tests can only be performed using methods from the standard EN 62321. XRF screening, which was and often is used as an indicator of the restricted substance presence is not one of such methods. It can be used only for preliminary evaluation purposes or as a part of a risk assessment of a component.

Once the documents for materials, parts and sub-assemblies are collected and evaluated, the manufacturer can establish the technical documentation. It must contain a description of the product which should include an identified product category, since it will affect applicability of exemptions. The supporting documents should be unequivocally linked to the components they cover. This can be done by using the bill of materials where both supplier part numbers and manufacturer part numbers (if different) should be included.

The series production compliance is subject to inevitable changes both due to the fluid nature of the legislation and to modifications that may be done to the end product and its components. Both types of changes may result in a product no longer being compliant with its technical documentation and/or both not being compliant with the legislation. It is reasonable to incorporate RoHS compliance assessment into a normal engineering

change process and have a process where documentation is reviewed against the requirements it refers to. Such review is best done as a part of normal Quality management procedures.

The manufacturer remains fully responsible for the product's compliance with all of the RoHS requirements, both administrative and essential.

3.3 Responsibilities per Battery Directive

Batteries and accumulators, a very common component of many EEE, while exempt from RoHS restrictions, are subject to hazardous substance restrictions imposed by a designated piece of legislation – Battery Directive 2006/66/EC. The entity which first places EEE containing the battery on the EEA market will be considered a battery producer for the purposes of the Directive. The hazardous substances restrictions are only a minor part of the issues covered by the Battery Directive. The Directive applies to all the batteries and accumulators with general military and space applications exemptions, but the ones which can be used in the electrical and electronic equipment will fall under the category “portable batteries”.

In such batteries according to Article 4 of the Directive, it is prohibited to use mercury and cadmium (with the exception of batteries in cordless power tool until January 2017 and general exemptions for emergency and alarm systems and medical equipment). In addition to substance restrictions, the Directive prohibits landfilling of the batteries and requires labelling of mercury, cadmium and lead content when above the limit values: 0.0005% for Hg, 0.002% for Cd and 0.004% for Pb, and requires the producers to finance the take-back schemes. Article 16(1) permits the member states to exempt producers of small batches of batteries from the obligation to finance such schemes; however, the substance restrictions will apply in full.

Even though other hazardous substances are not directly restricted by the Battery Directive, the recycling targets and landfilling ban result in such hazardous substances not presenting environmental risks at the stage of waste, without imposing additional obligations for the manufacturer.

There are no additional procedural or administrative requirements for the manufacturer with respect to hazardous substances besides labelling.

4 Compliance with hazardous substances requirements: status and challenges

Non-compliances with substance-related regulations rarely cause market surveillance authorities to take restrictive measures towards EEE; just a few such cases were reported in Rapid Alert System for dangerous non-food products, where European market surveillance authorities exchange information. Does that mean the relevant rules are thoroughly followed? According to KEMI - Swedish Chemical Agency (2014a), out of 71 electrical products examined in 2013 in a survey of certain equipment groups' compliance to RoHS Directive, 14 were found to be non-compliant, with 6 out of them containing excessive amounts of restricted substances, giving a 8.5 % non-compliance rate with substances restrictions. The remaining 8 cases of non-compliances or 11.2 % were related to an insufficient and faulty documentation (Swedish Chemicals Agency, 2014a), which implies the manufacturer or importer either misunderstood the legal requirements and did not have the appropriate procedures in place to prevent hazardous substances finding way into their products or simply did not care.

The sample sizes do not permit to make statistically significant conclusions, but demonstrate that the non-compliant products are present in each year's samples. From the Table 2 it can be seen lead is the most common restricted substance found in EEE.

Table 2. Analyses of home electronics products (Swedish Chemicals Agency, 2014), p.17

Year	Number of analysed home electronic products	Proportion of home electronic products not meeting the substance requirements	Substance exceeding limit value
2008	69	13	Lead
2009	12	1	Lead
2010	50	10	Lead
2011	62	10	Lead, PBDE
2012	63	12	Lead, PBDE
2013	71	6	Lead

KEMI admits that substances will pose a problem primarily at the waste stage and therefore, the risks are so far removed in time from when the article is being placed on the market, manufacturers prefer to concern themselves with more current (and obvious) product risks. However, RoHS restricted substances do pose immediate health risks to the workers involved in manufacturing the component. But since it also happens almost exclusively outside of EU, it is just as well out of focus of EU EEE manufacturers.

Another study was carried out by the National Measurements Office (NMO) in the UK in which the assessment of electronic toys against RoHS and Battery Directive was performed in 2015, and a 40% rate of non-compliance with either the substance content or marking requirements was discovered. No break-down of type of non-compliances was provided. The study covered only 15 products, therefore the results can hardly be used as indicative of entire EEE industry (NMO, 2015).

The studies on restricted substances are often non-comprehensive and tend to focus on smaller groups of products. Therefore, the results vary greatly, but the overall tendency stays the same – there is no full compliance in sight.

Despite the compliance challenges, the overall impact of RoHS legislation is significant. Already in 2008 "Study of the RoHS and WEE Directives" by Arcadis/Ecolas (2008), which dealt with the impact of the previous edition of RoHS Directive from the year 2002, found that lead use has been reduced by 82700 tonnes, cadmium by 14 200 tonnes, mercury by 9 500 tonnes and octa-BDE which was already banned before introduction of RoHS, continued reducing in the waste stream.

Other effects might be sometimes ambiguous; lead-free solders, while reducing the toxicity of EEE at waste stage and its aquatic toxicity, cause among other effects a 40% increase of energy consumption in manufacturing. Lead-free solder also causes reliability issues in the equipment and therefore increases the overall volumes of e-waste. This is due to the different properties of a replacement soldering mixture, which requires an increase in the soldering temperature by almost 30 °C and in turn a change in manufacturing processes which the components were not designed to withstand. Cracking, delamination and deformations of ceramic and plastic components during manufacturing turned out to be the result. Even when negative impacts are not immediately obvious, the reliability may be compromised and the equipment might fail sooner. However, this issue can be and is effectively solved through innovation and research. The overall impression of RoHS and its impacts is nonetheless positive within the electronics industry (Advanced Assembly, 2015).

Anticipated economic costs associated with the initial implementation of RoHS were offset by benefits for business, namely an increase of communication in supply chain, which is also instrumental in compliance with other legislation highly relying on it, such as

REACH, and increased potential benefits of EEE recycling due to lead-free solder containing gold and silver and overall increase of awareness of environmental issues in Europe and worldwide (RSJ Technical Consulting, 2008).

REACH implementation pattern in general resembles that of RoHS. According to the European Commission Memo (2010), REACH is ranked as the number one in the list of most burdensome legislation for small and medium sized enterprises, with product safety and market surveillance rules taking the third place, challenged only by VAT rules (European Commission, 2013b).

A number of extensive studies was carried out by the European Commission to assess the impact of REACH by its 5-year milestone in 2012. A Working Document, published in 2013, gave an insight into REACH's impact on electronics manufacturers (European Commission, 2013a).

By the end of 2011 a total of 5 346 substances were registered, increasing the quality and availability of information on the risks associated with them, making risk assessments easier and more straightforward. Articles producers have mainly benefitted from an increased information flow through the supply chain.

The communication of information requirement was originally deemed to bring both costs and benefits; some companies are successfully using REACH compliance as a marketing tool, though general public is mostly unaware of REACH. The increased communication in supply chain has not resulted in additional benefits, despite anticipations, but the better quality information on chemicals improved risk management on a company level.

Ad-hoc systems to achieve REACH compliance are eating up significant resources. The burden is inversely proportionate to the length of supply chain, therefore the EEE manufacturers fall into the worst end of the spectrum, together with aerospace and automotive industries. The need to set up designated IT solutions to process information flow resulted anywhere from thousands to millions euro. While automotive industry can benefit from unified International Material Data System (IMDS), the electronic industry is still relying on unconsolidated or partially consolidated solutions. Risk of disclosure of the proprietary information while complying with the communication requirement has been identified in the study, and again it is hitting smaller companies the hardest. Non-EU

suppliers have been reported to cease their operations on the EEA market due to their internal confidentiality policies prohibiting such levels of information disclosure.

The total costs of this requirement were identified as coming right after the registration costs, thus as a whole financially placing the downstream users of substances with the least expertise and influence over the chemical composition of their products financially at the same scale as the large chemical companies. The costs are attributed to the need to seek external solutions due to the lack of expertise inside the company. However, the electronics industry was not in the worst place, since they had to comply with RoHS prior to the introduction of REACH legislation and have generally followed the pattern.

Another negative effect rises from the competition on non-EU markets, where local producers do not have to bear costs of REACH compliance. This situation is, however, turning into a competitive advantage with more and more countries introducing REACH- and RoHS-like legislation.

The major overall benefit has been identified as the intensified information flow back from the downstream users of chemicals (who may use them in the process of manufacturing of articles) back to the chemicals manufacturing companies. This has generated a communication path for data on actual uses, exposure scenarios and risks and appropriateness of proposed risk management measures.

5 Discussion and conclusions

The complex nature of the regulatory situation the manufacturer finds itself in when dealing with substance requirements has led to the rise of demand for environmental compliance professionals within the industry. The specific penalties for breaking the legislation of hazardous substances are defined at national levels, based on the principle of proportionality of the penalty to the degree of a risk imposed by non-compliance. In general, the penalties include a ban from placing the product on the market, withdrawal from the market or recall from customers. Even though the probabilities of such penalties being imposed for substance non-compliance are perceived as rather low within the industry, manufacturers prefer to establish some sort of a compliance scheme to minimise such risks.

Larger international companies tend to derive their own internal environmental specifications - an internal set of documents with a comprehensive list of regulated substances, aggregated from national requirements in all countries of presence, a specific reporting procedure for suppliers and supplier obligations documents, such as a supplier's code of conduct or general terms and conditions, incorporated by reference in contracts with suppliers. Such companies as Motorola Solutions Inc. (MSI) or ABB have enough market presence to pressure suppliers into compliance with their specific customer requirements. Such specifications, like both W18 specification from MSI (Motorola Solutions, 2016) and a List of Prohibited and Restricted Substances from ABB (2016) include only the chemicals that can potentially be present in EEE, manufactured by the specification issuer.

Since only a fraction of, for example, REACH substances is restricted for use in EEE and can be found in EEE as intentionally added constituents or impurities, such aggregated lists are significantly shorter than their source regulations combined. They usually specify the basis for inclusion of such substance in their lists. In the absence of concrete readily available information, it can be speculated that the preparation of such internal specifications and the implementation of respective procedures would require financial inputs far beyond the reach of most, including large, companies. The need to maintain entire departments to process such a massive information flow is another added cost.

The other option would be to resort to a "turnkey" solution, where the substance compliance is fully outsourced to an external service provider. Such IT-based external solutions, for example BOMCheck (BOMCheck.net, 2016), which strives to become an equivalent to the Automotive industry-wide unified International Material Data System (IMDS), or Accent Compliance (Assentcompliance.com, 2016), provide data collection, analysis and reporting services and either take over the entire compliance management or provide detailed guidance on the parts of assessment procedures that the manufacturer carries out internally. These solutions heavily rely on full material disclosure procedures, where suppliers provide chemical compositions of their products. Since this process is often laborious and time consuming for the supplier, the temptation is high to rely on guesswork while filling out such full material disclosure requests. Intellectual property protection might be compromised as well, as some companies might prefer not to release sensitive information on their equipment components. The benefits, however, are obvious – decreased workload for employees and no need to maintain the in-house expertise level. The price levels are a lot more affordable; BOMCheck would charge 300 euros

annually for a supplier's account (for the manufacturer it is free), but the costs of supplier's efforts to collect the required information are of course not demonstrated. Another serious benefit is the possibility to assess compliance with the pending new substance restrictions in advance.

Smaller companies still often resort to ad-hoc solutions, in favour of having processes integrated with quality management systems, addressing substance compliance often late in the design or redesign process. This approach tends to be rather reactive, than proactive. It is, however, still in use, when the cost of non-compliance evaluated against its risk is perceived to be lower than investments into establishing compliance procedures.

An overall impression within the industry, as substantiated by multiple studies, is that the regulatory efforts for hazardous substances in electronics in Europe have ultimately been a success. EU regulators have successfully found a balance between the economic requirements of the single market and need to protect human health and environment from the detrimental effects of hazardous chemicals in a major waste stream. The challenges with compliance can largely be attributed to relative novelty of the substance legislation. As the awareness level within the industry rises, and market surveillance authorities learn to identify non-compliance risks, the situation is bound to improve. As a further recognition of the efforts of EU legislators, multiple REACH- and RoHS-like regulations are being created worldwide.

Responsible and coordinated efforts of regulatory and market surveillance authorities along with the industry, even as previously unconcerned with environmental impact of chemicals, as the electronic industry, can lead to a marked improvement in state of affairs at a bearable cost in just over a decade. The ambitious goals of effectively protecting the environment and human health from the harmful chemicals through responsible management approach can ultimately be achievable.

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